

REMARKS

Entry of this amendment is respectfully requested. Prior to this amendment, Claims 1-10, 17-46 and 51-63 were pending. Claims 5, 17-19, 34, 39-40, 51-52 and 60-63 are cancelled herein and Claims 1-4, 6-10, 23, 41, 43-46, and 57 are amended herein. The amendments to the claims do not introduce new matter into the specification and are fully supported by the specification as originally filed.

Entry of the above amendments to the claims is respectfully requested. Reconsideration of Claims 1-4, 6-10, 20-33, 35-38, 41-46 and 53-59 is respectfully requested in view of the above amendments and the following remarks.

Rejection of Claims 60-63 under 35 U.S.C. 112, ¶1

The Examiner rejected Claims 60-63 under 35 U.S.C. 112, ¶ 1, as failing to comply with the enablement requirement. Although Applicants respectfully submit that one skilled in the art would reasonably expect that the compounds of the invention would be useful in treating solid tumors, AIDS, ischemia reperfusion injury and cardiac arrhythmias, especially in view of the teachings of the specification, in the interest of furthering the prosecution of the application, Applicants have deleted Claims 60-63, thereby rendering moot this rejection with respect thereof.

Rejection of Claims 1-10, 17-39, 41-46 and 51-63 under 35 U.S.C. 112, ¶1

The Examiner rejected Claims 1-10, 17-39, 41-46 and 51-63 under 35 U.S.C. 112, ¶1, as failing to comply with the written description requirement. In particular, the Examiner contends that:

*The present specification lacks an adequate description of the claimed subject matter because there is insufficient descriptive support for the term "prodrugs". The present specification lacks any correlation between said functional characteristic and any structure(s) and, thus, the skilled artisan would be unable to envision the compounds necessary for practice of the claimed invention. Thus, the claims fail to comply with the written description requirement.*

Applicants respectfully traverse this rejection for the following reasons.

The term "prodrugs" is defined on pages 26-27 of the Specification in sufficient detail for one skilled in the art to reasonably envision what Applicants intended by the use of this term in describing the scope of invention. However, in the interest of furthering the prosecution of this application, Applicants have deleted the term "prodrugs" from Claim 1, thereby rendering moot this rejection with respect to remaining claims 1-4, 6-10, 20-33, 35-38, 41-46 and 53-59. Applicants reserve the right to pursue the deleted subject matter in either a timely filed continuation application or in co-pending application, Serial No. 10/258,950.

Accordingly, in view of the above amendments to the claims, Applicants respectfully submit that Claims 1-4, 6-10, 20-33, 35-38, 41-46 and 53-59 meet the requirements of 35 U.S.C. 112, ¶1.

Rejection of Claims 1-10, 17-39, 41-46 and 51-63 under 35 U.S.C. 112, ¶2

The Examiner rejected Claims 1-10, 17-39, 41-46 and 51-63 under 35 U.S.C. 112, ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner contends that:

*The instant claims recite "prodrugs". However, the present specification does not provide the skilled artisan with a clear understanding of what is encompassed by said term. Therefore, the skilled artisan would be unable to determine the metes and bound of the claimed invention.*

As noted above, Applicants have amended Claim 1 to delete the term "prodrugs", thereby rendering moot this rejection with respect to the cited claims.

In addition, the Examiner contended that:

*Claim 57 also recites "including but not limited to" which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.*

Applicants have amended Claim 57 to remove this term, thereby rendering moot this rejection with respect thereof.

Double Patenting

The Examiner maintained the provisional rejection of claim 52 under 35 U.S.C. 101 over claim 68 of co-pending Application No. 10/258,950. Applicants continue to reserve the

right to address this issue upon the issuance of any conflicting claim in the cited co-pending Application.

The Examiner also maintained the provisional rejection of claims 1-10, 17-46 and 53-63 under the judicially created doctrine of obviousness-type double patenting over claims of co-pending Application No. 10/258,950. Applicants continue to reserve the right to address this issue upon issuance of any conflicting claim in the cited co-pending Application.

Rejection of Claims 1, 2, 5-7, 28, 30, 33, 34, 36, 40-43 and 53 under 35 U.S.C. 102(b)

The Examiner rejected Claims 1, 2, 5-7, 28, 30, 33, 34, 36, 40-43 and 53 under 35 U.S.C. 102(b) as being anticipated by US 5,856,535 ("Zasloff"). In particular, the Examiner contends that:

*Zasloff et al. teach aminosterol esters having hydrogen or hydroxyl in the 6 and/or 7 positions (see the entire article, especially col. 2, line 1 - col. 10, line 68, see compounds such as #355, 356, 380, 394-396, 409-411, 431 and 432). The reference teaches various properties of the compounds such as its antimicrobial activity (see col. 46, Properties of the Aminosterol Esters). The compounds and compositions taught by the reference are encompassed by the instant claims.*

Applicants respectfully traverse this rejection for the following reasons:

Without acquiescing to the Examiner's reasons for this rejection and in the interest of furthering the prosecution of this application, Applicants have amended the pending claims to be directed to compounds wherein the carbon at numeral 17 is substituted only with  $-C(R^5)(R^5)(C(R^5)(R^5))_n-$  or  $-(O(C(R^5)(R^5))_nO)-$  wherein n ranges from 1 to about 6 and where  $R^5$  is as defined in Claim 1. Zasloff does not disclose any compounds having such substitution. Accordingly, Applicants respectfully submit that remaining Claims 1, 2, 6-7, 28, 30, 33, 36, 41-43 and 53 are not anticipated under 35 U.S.C. 102(b) in view of the teachings of Zasloff and respectfully request the withdrawn of this rejection with respect thereof.

Rejection of Claims 1-7, 18, 36, 40, 41 and 53 under 35 U.S.C. 102(e)

The Examiner rejected Claims 1-7, 18, 36, 40, 41 and 53 under 35 U.S.C. 102(e) as being anticipated by US 6,046,185 ("Burgoyne"). In particular, the Examiner contended that:

*Burgoyne et al. teach 3-oxime-6,7-bis(acetyloxy)-pregnan-3-one and its use in the preparation 6,7-oxygenated [sic] steroids (see col. 210, compound*

357). *The compound and composition taught by the reference are encompassed by the instant claims.*

Applicants respectfully traverse this rejection for the following reasons:

As noted above, Applicants have amended the claims to be directed to compounds wherein the carbon at numeral 17 is substituted only with  $-C(R^5)(R^5)(C(R^5)(R^5))_n-$  or  $-(O(C(R^5)(R^5))_nO)-$  wherein n ranges from 1 to about 6 and where  $R^5$  is as defined in Claim 1. The 3-oxime compound disclosed in Burgoyne does not have this substitution at the carbon corresponding to the carbon at numeral 17 in the instant claims. Accordingly, Applicants respectfully submit that remaining Claims 1-4, 6-7, 36, 41 and 53 are not anticipated under 35 U.S.C. 102(e) in view of the 3-oxime compound disclosed in Burgoyne and respectfully request the withdrawal of this rejection with respect thereof.

Rejection of Claims 1, 2, 5-7, 28, 30, 33, 34, 36, 40-43, 53, 60 and 61 under 35 U.S.C. 103(a)

The Examiner rejected Claims 1, 2, 5-7, 28, 30, 33, 34, 36, 40-43, 53, 60 and 61 under 35 U.S.C. 103(a) as being unpatentable over Zasloff. In particular, the Examiner contends that:

*Zasloff et al. teach aminosterol esters having a hydrogen or hydroxyl in the 6 and/or 7 positions (see the entire article, especially col. 2, line 1 - col. 10, line 68, see compounds such as #355, 356, 380, 394-396, 409-411, 431 and 432). The reference teaches various properties of the compounds such as antimicrobial activity (see col. 46, Properties of the Aminosterol Esters).*

*The instant claims differ from the reference by reciting compounds not exemplified by the reference, i.e., compounds having a hydroxyl group at both the C6 and C7 positions. However, the prior art teaches C6 and C7 can have one of two groups attached thereto. The reference also exemplifies hydroxyl at both the C6 and C7 positions. Based on the teachings of the prior art and the limited substituents at C6 and C7, the ordinary artisan in the art would readily envisage the exemplified prior art compounds having a hydroxyl group at both the C6 and C7 positions with the reasonable expectation that the compounds would be useful as taught by Zasloff et al.*

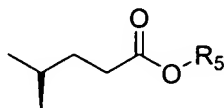
*Claims 60 and 61 further differ from the reference by reciting the treatment of solid tumours and AIDS.*

*However, Zasloff et al. teach aminosterols are known to have anti-angiogenic properties and thus, useful in treatment of cancers and viral infections such as HIV. Thus, the skilled artisan would have the reasonable expectation that the aminosterols taught by Zasloff would be anti-angiogenic and, thus, useful in the treatment of solid tumours and AIDS as recited by the instant claims. The*

*motivation would be based on the desire to obtain additional aminosterols useful in the treatment of cancers and viral infections as known in the art.*

Applicants respectfully traverse this rejection for the following reasons:

As noted above, Applicants have amended the claims to be directed to compounds wherein the carbon at numeral 17 is substituted only with  $-C(R^5)(R^5)(C(R^5)(R^5))_n-$  or  $-(O(C(R^5)(R^5))_nO)-$  wherein  $n$  ranges from 1 to about 6 and where  $R^5$  is as defined in Claim 1. Such substitution on the carbon at numeral 17 is not disclosed in Zasloff, as discussed above, nor is it suggested by any means. The compounds in Zasloff only have one substitution at the carbon corresponding to the carbon at numeral 17 in the instant application, and that substitution is the following:



where  $R_5$  is a  $C_1$  to  $C_{12}$  alkyl group.

There is no disclosure or suggestion in Zasloff that would lead one skilled in the art to arrive at the instantly claimed compounds wherein the substitution at the carbon at numeral 17 is a spiro-carbocyclic or spiro-heterocyclic compound. Accordingly, Applicants respectfully submit that Claims 1, 2, 6-7, 28, 30, 33, 36, 41-43, and 53 are not rendered obvious under 35 U.S.C. 103(a) by the teachings of Zasloff and respectfully request that this rejection be withdrawn in respect thereof.

#### Additional Amendments to the Claims

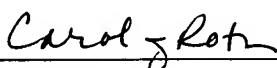
In addition to the amendments to the Claims discussed above to further the prosecution of this application, Applicants have amended the claims to place them in better condition for allowance. Such amendments are fully supported in the specification as originally filed and do not constitute the introduction of any new matter into the specification. In addition, Applicants have removed subject matter from the claims that will be pursued in the co-pending application, Serial No. 10/258,950, particularly subject matter relating to compounds wherein  $R^1$  and  $R^2$  form, or are part of, a heterocyclic ring.

Conclusion

In view of the foregoing arguments and amendments, Applicants respectfully submit that all of the remaining claims are clearly allowable. Favorable consideration and an early Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,  
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